

Amendments to the Drawings

The attached replacement sheets of drawings, which include Figures 1, 2, and 23, replace the original drawings. The replacement drawings are being submitted to remove the frames in order to comply with 37 C.F.R. § 1.84(g).

Attachment: Replacement Sheets

Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 10, 14, 15, 17, 18, 21 and 41-48 are pending in the application, with claims 10, 17, 18 and 21 being the independent claims. Claims 1-9, 11-13, 16, 19, 20 and 22-40 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 41-48 are sought to be added. Support for the new claims may be found in original claims 10, 17, 18, and 21 and in the specification at page on page 10, lines 5-6. Claims 10, 17, 18 and 21 are sought to be amended. Support for the amendment to the claims may be found in the claims as originally filed and in the specification at page 21, line 4 through page 25, line 24, Examples 1-4 and Figure 1. Support for SEQ ID NO:30 may be found in Figure 1 which shows that the Hd-Zip domain of Hahb-4 ends at amino acid 115 of SEQ ID NO:24. Thus, SEQ ID NO:30 encompasses amino acids 116 through 181 of SEQ ID NO:24. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Summary of the Office Action

In the Office Action dated February 22, 2008, the Examiner has made two objections to the specification, one objection to the drawings, sixteen objections of the

claims and five rejections of the claims. Applicant respectfully offers the following remarks concerning each of these elements of the Office Action.

III. The Objections to the Specification Should Be Withdrawn

In section 2 of the Office Action at pages 2-3, the specification was objected to for failing to identify certain nucleotide sequences by sequence identifiers as required by 37 C.F.R. § 1.821. Applicants have amended the specification to insert the required sequence identifiers. Thus, this objection has been accommodated and should be reconsidered and withdrawn.

In addition, filed herewith is a Substitute Sequence Listing in paper form and in computer readable form. The Substitute Sequence Listing is being filed to add sequences from the as-filed specification and drawings. Support for these sequences may be found in the specification and drawings at page 4, lines 6-7 and Figure 1. In accordance with 37 C.F.R. §§ 1.821-1.825, the paper and computer readable forms of the Substitute Sequence Listing submitted herewith are identical and contain no new matter. The specification has been amended to direct the entry of the Substitute Sequence Listing. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Finally, in section 3 of the Office Action at page 3, the Examiner has objected to the specification for the misspelling of "alleloe." Applicants have corrected the spelling of "alleloe" to "allele." Thus, Applicants respectfully request that the Examiner reconsider and withdraw the objection.

IV. The Objections to the Drawings Should Be Reconsidered and Withdrawn

In section 4 of the Office Action at pages 3-4, Figures 1, 2 and 20-23 were objected to for allegedly failing to comply with 37 C.F.R. § 1.84(g) because the figures are framed. With regard to Figures 1, 2 and 23, Applicants submit three sheets of formal replacement drawings in order to comply with 37 C.F.R. § 1.84(g). Identification of the replacement drawing sheets submitted herewith are provided in accordance with 37 C.F.R. §§ 1.84(c) and 1.121(d). Acknowledgement of the receipt, approval, and entry of the replacement drawing sheets into this application are respectfully requested.

However, with regard to Figures 20-22, Applicants respectfully request reconsideration of this objection. Figures 20-22 are photographs and not text. If the lines around these figures were removed, it would not be apparent where the photograph ends. Thus, Applicants respectfully request that the Examiner reconsider and withdrawal the objection of Figures 20-22.

V. The Objections to the Claims Should Be Withdrawn

In section 5 of the Office Action at pages 4-6, claims 1-4, 6-12 and 16-21 have been objected to due to informalities. However, as indicated above, Applicants have cancelled claims 1-4, 6-9, 11-12, 16, 19 and 20, thus rendering moot the objection as applied to these claims.

Claims 10, 17, 18 and 21 were objected to for reciting "comprising." Claims 10, 17, 18 and 21 have been amended to remove the language. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the objection.

Claim 21 was objected to for grammatical errors. Claim 21 has been amended to correct these grammatical errors. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the objection.

VI. The Rejection under 35 U.S.C. § 112, Second Paragraph is Moot

In section 6 of the Office Action at pages 6-7, claim 8 has been rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for providing insufficient antecedent basis. Applicants respectfully disagree. However, as indicated above, claim 8 has been cancelled without prejudice or disclaimer thereof. Thus, this rejection is rendered moot. Reconsideration and withdrawal of the rejection are respectfully requested.

VII. The Rejections Under 35 U.S.C. § 112, First Paragraph are Traversed

A. Enablement

In section 7 of the Office Action at pages 7-15, claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly would not be enabling for “(a) a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor *Hahb-4*, and (b) a nucleic acid sequence having a fragment of SEQ ID NO:1 or SEQ ID No:2.” *See* Office Action at page 7. Applicants respectfully disagree. However, as indicated above, Applicants have cancelled claims 1-9, 11-13, 16, 19, and 20, thus rendering moot the rejection as applied to these claims. In addition, in an effort to facilitate prosecution, and not in acquiescence to the Examiner’s rejection Applicants have amended claims 10, 17, 18 and 21 to remove the “functionally active

fragment or variant thereof” and “fragments thereof” language. However, inasmuch as the amended claims incorporate similar language from the previously pending claims to which the Examiner rejected, Applicants respectfully traverse the rejection with the following arguments.

First, Applicants agree with the Examiner that in order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, the claimed invention must be enabled so that a person of skill in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). However, some experimentation, *e.g.*, testing and screening, even a considerable amount in order to make the invention, is not "undue" if, *e.g.*, it is merely routine. *Id.* Applicants assert that it would require no more than routine experimentation for a skilled artisan to practice the full scope of the claimed invention in view of the teachings in the specification and the knowledge available in the art. Thus, the enablement requirement of 35 U.S.C. § 112, first paragraph, is fully satisfied for the currently pending claims.

As indicated above, amended claims 10 and 17 are directed to a transgenic plant or plant seed stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant or seed and the expression of the nucleic acid provides an increased tolerance to drought as compared to a wild type variety of such plant or seed under the same conditions. Amended claim 18 is directed to a plant host cell transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3'

DNA sequence attached to SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant host cell. Amended claim 21 is directed to a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to SEQ ID NO:30 in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

The Examiner asserts that "the instant specification fails to provide guidance on how to make a nucleic acid sequence encoding a functionally active fragment or variant of transcription factor Hahb-4 having the functional activity (e.g. drought tolerance) of Hahb-4 protein." Office Action at page 9. The Examiner further asserts that "it would be highly unpredictable that a fragment of Hahb-4 protein having DNA (5'-CAAT(A/T)ATTG-3') binding activity alone would be sufficient for producing an environmental stress tolerance when overexpressed in a plant." Office Action at page 13. While Applicants agree with the Examiner that altering the sequence downstream of the Hd-Zip domain of Hahb-4 may be unpredictable, Applicants respectfully assert that making and using a transgenic plant, plant seed, plant host cell stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence *attached to* SEQ ID NO:30, would not require undue experimentation.

As noted above, SEQ ID NO:30 defines the exact polypeptide sequence of HAHB-4 (SEQ ID NO:24) immediately following the Hd-Zip domain through the end of the protein, *i.e.*, amino acids 116-181 of SEQ ID NO:24. Thus, Applicants respectfully

point out that the claims, as currently presented, require that the expressed protein contains not only a functionally defined Hd-Zip binding domain, but also the sequence-defined downstream region of the Hahb-4 protein (SEQ ID NO:30). Therefore, Applicants respectfully assert that the transgenic plants or plant seeds expressing such a protein would exhibit an increased tolerance to drought. Thus, to practice the full scope of the claimed invention, the skilled artisan would only need to be able to: (a) obtain nucleic acid molecules that encode polypeptides comprising a Hd-Zip domain attached to SEQ ID NO:30, (b) test them for the ability to bind to a 5'-CAAT(A/T)ATTG-3' DNA sequence, (c) stably transform a transgenic plant, plant seed, or plant host cell with a nucleic acid molecule that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence, and (d) express the nucleic acid molecule in the transgenic plant, plant seed or plant host cell. All of these processes would be routine in the art and are readily taught in the specification.

Applicants respectfully point out that in order to practice the claimed invention, a skilled artisan would not need to be able to predict the structural and/or functional consequences of particular mutations or base changes, *i.e.*, which particular amino acids to change within the Hd-Zip domain. However, even though Applicants are not required to point out which mutations to make, the specification clearly describes examples of Hd-Zip domains and includes an alignment showing the conserved residues within the Hd-Zip domain. *See, e.g.*, the specification at page 10, lines 4-11 and Figure 1. Thus, the specification clearly lays out the amino acid residues that would be amenable to alteration based on the structure of the Hd-Zip domain.

Furthermore, the structure of Hd-Zip domains was well known in the art when the present application was filed. *See Sessa et al.*, J. Mol. Biol. 274:303-309 (1997) (copy attached as Exhibit 1). *Sessa et al.* provides a detailed analysis of the structure of the Hd-Zip domain present in numerous polypeptides, and the residues necessary for the DNA-binding function. Thus, one of skill in the art would know what substitutions, deletions, and insertions could be made to the nucleic acid sequence, but still retain the function of the Hd-Zip domain. Therefore, in addition to the guidance provided in the specification for the conserved residues of the Hd-Zip domain, knowledge in the art also provides information pertaining to the conserved residues of Hd-Zip domains.

Once obtained, nucleic acid molecules that encode polypeptides comprising a Hd-Zip domain attached to SEQ ID NO:30 can easily be tested for the ability to bind a 5'-CAAT(A/T)ATTG-3' DNA sequence using routine techniques. For example, the present specification teaches assays, such as an electrophoretic mobility shift assay (EMSA) that could be routinely used by one of ordinary skill in the art to test whether variants had the required function. *See* specification at page 19, line 16 through page 20, line 8 and page 39, line 10 through page 40, line 2. Thus, the full range of nucleic acid molecules encompassed by the pending claims can be made and analyzed by persons of ordinary skill in the art using only routine methods and experimentation.

Admittedly, the above processes may result in the production of nucleic acid molecules that encode proteins comprising a Hd-Zip domain attached to SEQ ID NO:30, but *do not* bind a 5'-CAAT(A/T)ATTG-3' DNA sequence. The skilled artisan, however, would be able to easily identify and discard such non-active molecules that do not fall within the scope of the claimed invention. Screening for molecules that possess a

particular activity is common in the biological arts. Experimentation, even complex experimentation, is not undue if the art typically engages in such experimentation. *See In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985); *see also Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. For example, in concluding that practicing the claimed invention would not require undue experimentation, the court in *Wands* stated that, "[t]he nature of monoclonal antibody technology is that it involves screening hybridomas [often hundreds at a time] to determine which ones secrete antibody with desired characteristics[, and p]ractitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody." *Wands*, 858 F.2d at 738, 740, 8 USPQ2d at 1405, 1406.

Thus, the uncertainty that may be associated with predicting protein function from sequence data is of little relevance in an analysis of the enablement of Applicants' claims. Much like the practitioners in *Wands* screening hundreds of hybridomas for monoclonal antibodies with the desired characteristics, a skilled artisan would be expected to engage in screening for nucleic acid molecules that encode proteins comprising a Hd-Zip domain attached to SEQ ID NO:30 and bind a 5'-CAAT(A/T)ATTG-3' DNA sequence. Such screening, even if it resulted in the identification of a molecule not having the desired activity, would be considered routine in the art and would be acknowledged as an integral part of making the nucleic acid molecules.

In view of the forgoing discussion, Applicants submit that a person having ordinary skill in the art, in view of the teachings of the specification, would be able to make and practice the full scope of Applicants' claimed invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

B. Written Description

In section 8 of the Office Action at pages 15-19, claims 1-21 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to meet the written description requirement. As indicated above, Applicants have cancelled claims 1-9, 11-13, 16, 19, and 20, thus rendering moot the rejection as applied to these claims. In addition, in an effort to facilitate prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amend claims 10, 17, 18 and 21 to remove the "functionally active fragment or variant thereof" and "fragments thereof" language. However, inasmuch as the amended claims incorporate similar language from the previously pending claims to which the Examiner rejected, Applicants respectfully traverse the rejection with the following arguments.

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one skilled in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. In the instant case,

Applicants assert that the Examiner has not met this burden with regard to the currently pending claims.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. In addition, the written description requirement must be viewed in light of the state of the art at the time of filing. *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed Cir. 2005). Applicants submit that, when viewed in light of the state of the art at the time of filing the present application, the specification fully supports the presently claimed invention.

The Examiner asserts that "[t]he specification does not describe the structure of Hahb-4 variant(s), and thus their function is unknown." Office Action at page 18. The Examiner further asserts that "[t]here is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional (environmental stress tolerance) activity of the Hahb-4 protein." Office Action at page 18. With regard to the currently pending claims, Applicants respectfully disagree.

Applicants respectfully contend that the specification as filed provides an adequate written description for transgenic plants, plant seeds, and plant host cells stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence *attached to* SEQ ID NO:30.

As discussed above, SEQ ID NO:30 defines the exact polypeptide sequence of HAHB-4 (SEQ ID NO:24) immediately following the Hd-Zip domain through the end of

the protein, *i.e.*, amino acids 116-181 of SEQ ID NO:24. Thus, Applicants respectfully point out that the claims, as currently presented, require that the expressed protein contains not only a functionally defined Hd-Zip binding domain, but also the sequence-defined downstream region of the Hahb-4 protein (SEQ ID NO:30). Therefore, Applicants respectfully assert that the transgenic plants or plant seeds expressing such a protein would exhibit an increased tolerance to drought due to the requirement for the specified sequence of SEQ ID NO:30.

With regard to the functionally defined Hd-Zip domain, the specification provides considerable guidance about Hd-Zip domains and includes an alignment showing the conserved residues within the Hd-Zip domain. *See, e.g.*, the specification at page 10, lines 4-11 and Figure 1. Thus, the specification clearly lays out the amino acid residues that would be amenable to alteration based on the structure of the Hd-Zip domain, without affecting the ability of the protein to bind to the 5'-CAAT(A/T)ATTG-3' DNA sequence.

In addition, as indicated above, the structure of Hd-Zip domains was well known in the art when the present application was filed. *See Sessa et al.*, J. Mol. Biol. 274:303-309 (1997) (copy attached as Exhibit 1). *Sessa et al.* provides a detailed analysis of the structure of the Hd-Zip domain present in numerous polypeptides, and the residues necessary for the DNA-binding function. Given that the skilled artisan would have been familiar with this common structural core among Hd-Zip domains and given the teachings of the present application, the skilled artisan could clearly envision the sequences that would retain the functional requirement of binding to the 5'-CAAT(A/T)ATTG-3' DNA sequence. As noted in *Capon*, when the prior art includes

the relevant information, "precedent does not set a *per se* rule that the information must be determined afresh." *Capon*, 418 F.3d at 1358. Thus, it would be readily apparent to the skilled artisan that the Applicants had "invented what is claimed" *Vas-Cath*, 935 F.2d at 1563. Accordingly, one skilled in the art, enlightened by the teachings of the present application and the knowledge in the art, could readily envision all of the various polypeptide sequences of the specified polypeptides.

Applicant asserts that the specification conveys with reasonable clarity that the Applicant was in possession of the claimed invention and that the claims are fully supported by the specification. For all of the above reasons, Applicant respectfully asserts that the present specification provides sufficient written description to convey to one of ordinary skill that Applicant had possession of the full scope of the claimed invention upon filing of the application. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, are respectfully requested.

VIII. The Rejection Under 35 U.S.C. § 102 is Rendered Moot

In section 9 of the Office Action at pages 19-21, claims 1-8 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Gago *et al.* (*Plant, Cell and Environment* 25:633-640 (2002)) (hereinafter "Gago"). However, as indicated above, claims 1-8 have been cancelled without prejudice or disclaimer thereof. Thus, this rejection is rendered moot. Reconsideration and withdrawal of the rejection is respectfully requested.

IX. The Rejection Under 35 U.S.C. § 103 is Traversed

In section 11 of the Office Action at pages 22-25, claims 9-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Gago in view of Bidney *et al.* (U.S. Patent No. 6,265,638) (hereinafter “Bidney”). As indicated above, solely in an effort to advance prosecution, and not in acquiescence to any reasoning underlying the Examiner's rejection, Applicants have canceled claims 9, 11-13, 16, 19, and 20 without prejudice or disclaimer of the subject matter therein. Hence, the objection to these claims has been rendered moot. Applicants respectfully traverse this rejection with respect to the remaining claims.

The Examiner asserts that:

it would have been prima facie obvious to one of ordinary skill in the art to transform any plant species with a nucleic acid sequence encoding Gago *et al.* Hahb-4 protein using any method of plant transformation including the one taught by Bidney *et al.* to obtain a transgenic plant...overexpressing Hahb-4 protein.

Office Action at pages 24-25. The Examiner further asserts that because:

Gago *et al.* clearly teach that Hahb-4 protein is induced...in a plant...in response to drought or water stress, and Hahb-4 protein regulates the expression of drought inducible promoter(s) through its binding with the dehydration responsive elements present within said promoter, one of ordinary skill in the art would have been motivated to overexpress a nucleic acid sequence encoding...Hahb-4 protein in any plant...for the purpose of obtaining a water stress (drought) tolerant transgenic plant with reasonable expectation of success.

Office Action at page 25. Applicants respectfully disagree with these statements.

The United States Supreme Court addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007). The Court stated that the

Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966) factors still control an obviousness inquiry. Those factors are: 1) "the scope and content of the prior art"; 2) the "differences between the prior art and the claims"; 3) "the level of ordinary skill in the pertinent art"; and 4) objective evidence of nonobviousness (*KSR*, 127 S.Ct. at 1734 (quoting *Graham*, 383 U.S. at 17-18)).

The USPTO has recently published guidelines for Examiners in determining whether claims are non-obvious under the *KSR* holding. 72 FR 57526. In particular, the Office requires that Examiners articulate, in the record, specific findings of fact which, in view of the legal considerations under *Graham*, would render the claimed invention obvious. While the Office sets forth a number of rationales by which a determination of obvious may be made (*Id.* at 57529), a common thread throughout requires that the prior art, in combination with the knowledge ascribed to the person of ordinary skill in the art, provide sufficient information to make the claimed invention fully and easily predictable.

Here, as detailed below, the Examiner has not established a *prima facie* case of obviousness because the Examiner has not adequately shown that the claimed invention was fully and easily predictable.

Furthermore, post-*KSR* decisions by the Federal Circuit clearly indicate that the requirement for showing a reasonable expectation of success still plays an important role in an obviousness determination and, further, that evidence demonstrating a lack of a reasonable expectation of success must be considered. *See, e.g., Takeda Chemical Industries, Ltd. v. Alphapharm PTY., LTD*, 492 F.3d 1350, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007) (holding that even though a compound similar to the claimed anti-diabetic compound, was known in the prior art, one of ordinary skill would not have had a

reasonable expectation of success in obtaining the claimed invention); and *Forest Laboratories, Inc. v. IVAX Pharmaceuticals, Inc.*, No. 2007-1059, slip op. (Fed. Cir. Sept. 5, 2007) (holding that one of ordinary skill would not have had a reasonable expectation of success in attempting to separate a substantially pure enantiomer even though the racemic mixture was known in the art). In addition, objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts must be considered in every case in which they are present. *See* MPEP §2141.

Here, even assuming *arguendo* that the Examiner has established a *prima facie* case of obviousness, Applicants assert, as detailed below, that the *prima facie* case of obviousness is rebutted by the presentation of failure of others, unexpected and advantageous properties, and long-felt need of the claimed products and method.

A. The Examiner Failed to Establish a Prima Facie Case of Obviousness

As indicated above, amended claims 10 and 17 and thus the remaining claims that depend therefrom are directed to a transgenic plant or plant seed stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant or seed and the expression of the nucleic acid provides an increased tolerance to drought as compared to a wild type variety of such plant or seed under the same conditions. Amended claim 18 is directed to a plant host cell transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2)

SEQ ID NO:30, wherein the nucleic acid molecule is expressed in the plant host cell.

Amended claim 21 is directed to a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

Gago does not disclose, suggest, or otherwise contemplate a transgenic plant, plant seed, or plant host cell that has been stably transformed with a nucleic acid molecule comprising a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30. In addition, Gago does not disclose, suggest, or otherwise contemplate that the expression of a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 in a transformed plant or plant seed will result in an increased tolerance to drought compared to a wild type plant or plant seed under the same conditions. Furthermore, Gago does not disclose, suggest, or otherwise contemplate a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30, expressing the nucleic acid in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

Gago only discloses that *Hahb-4* is upregulated in response to water stress. However, there is absolutely nothing in Gago to suggest that expression of *Hahb-4* would also confer tolerance to drought in sunflowers, let alone other plant species. Despite the Examiner's assertion to the contrary, at the time the application was filed, one of ordinary skill in the art would not have predicted that a transcription factor that is upregulated in response to water stress such as *Hahb-4* would thus also confer tolerance to drought. In support of this contention, Applicant provides herewith a Declaration under 37 C.F.R. § 1.132 of Federico Trucco, Ph.D. ("Trucco Declaration"). Indeed, as pointed out in the Trucco Declaration, transcription factors, including those induced by water stress, regulate a wide variety of target genes, many of which may not be involved in drought tolerance. Trucco Declaration at page 2. In addition, even if these transcriptional factors did regulate genes involved in drought tolerance, post-transcriptional modification to the transcription factor could be required in order to induce expression of the downstream target gene. Trucco Declaration at pages 2-3. Thus, in both instances, expression of the transcription factor would not result in a drought tolerant phenotype. Accordingly, based on the state of the art as at the time the application was filed, Applicants respectfully assert that it would not have been predictable that expression of a transcription factor, such as *Hahb-4*, induced in response to water stress would function to provide an increased tolerance to drought in a transgenic plant because there was not a finite number of predictable outcomes. Thus, in view of the unpredictability in correlating water stress induction with drought tolerance set forth in the Trucco Declaration, Gago fails to provide a reasonable expectation of success that the expression of the *Hahb-4* gene in a transgenic plant would result in a

transgenic plant that exhibited increase tolerance to drought as required by the claims. Thus, Gago is deficient as a primary reference upon which to base a *prima facie* case of obviousness.

These deficiencies are not cured by the disclosure of Bidney. Bidney discloses a method of transforming plants using *Agrobacterium*. Bidney does not disclose, suggest, or otherwise contemplate a transgenic plant, plant seed, or plant host cell that has been stably transformed with a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30. In addition, Bidney does not disclose, suggest, or otherwise contemplate that the expression of a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30 in a transformed plant or plant seed will result in an increased tolerance to drought compared to wild type plant or plant seed under the same conditions. Furthermore, Bidney does not disclose, suggest, or otherwise contemplate a method of producing a water stress tolerant transgenic plant by stably transforming a plant cell or cell culture with a nucleic acid sequence that encodes a protein comprising (1) a Hd-Zip domain that binds to a 5'-CAAT(A/T)ATTG-3' DNA sequence attached to (2) SEQ ID NO:30, expressing the nucleic acid in the plant cell or cell culture and regenerating the cell or cell culture into a plant.

Thus, Applicants submit that, upon careful analysis of the cited references and given the unpredictability in the field, the skilled artisan would have found no motivation to combine or modify the reference teachings with a reasonable expectation of success to

arrive at the claimed invention. Accordingly, a *prima facie* case of obviousness has not been established. Applicants respectfully request that the rejection be withdrawn.

B. The Claimed Invention Exhibits Unexpected Results and Long-Felt Need, and There was Failure by Others for the Claimed Invention.

Even assuming, *arguendo*, that the Examiner has established a *prima facie* case of obviousness, Applicants submit that secondary indicia such as unexpected results, long-felt need, and failure by others clearly rebut any such case.

As reaffirmed by the U.S. Supreme Court, courts are "to look at any secondary considerations that would prove instructive," when considering the obviousness of an invention. *KSR Int'l. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (April 30, 2007). For example, as set forth in M.P.E.P. § 2141(III), objective evidence or secondary considerations such as unexpected results and the failure of others is relevant to the issue of obviousness and must be considered in every case in which they are present. "Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987) (*emphasis added*).

The Trucco Declaration explains in detail that there was, and still is, a huge need to develop productive agronomically valued crops that are drought tolerant. Trucco Declaration at page 4. The Trucco Declaration further explains that despite previous failure by others to produce transgenic plants that are drought or water stress tolerant, the present invention provides multiple species of transgenic plants that are unexpectedly drought tolerant. Trucco Declaration at pages 4-6. First, the Trucco Declaration describes two *Arabidopsis* transcription factors that share homology with

Hahb-4 and are induced under water stress but fail to confer drought tolerance to transgenic plants. Trucco Declaration at page 4.

In clear contrast, as explained in the Trucco Declaration, the transgenic plants described in the present invention are unexpectedly drought tolerant. Trucco Declaration at page 5. In addition to the unexpected result that the expression of *Hahb-4* in a dicot (*Arabidopsis*) would result in the development of a drought resistant phenotype, Applicants also demonstrated, using greenhouse studies, that *Hahb-4* can be expressed in and produce a drought resistant phenotype in two different monocots. Trucco Declaration at page 6. Thus, the expression of *Hahb-4* in various species of plants has unexpectedly met a long-felt need of providing productive agronomically valued transgenic plants, which is strong evidence that the claimed composition is not obvious. In view of the foregoing remarks, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

X. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

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Prompt and favorable consideration of this Amendment and Reply is respectfully
requested.

Respectfully submitted,

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